

**On-Site Assessment Committee Teleconference
April 16, 1997**

The On-Site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Wednesday, April 16, 1997. Mr. Gary Bennett, Chair of the Committee, led the meeting. A list of participants is shown as Attachment A.

Mr. Gary Bennett reported that Ms. Jan Jablonski is now a full-time EPA employee. She will no longer be working as a consultant for the Assessor Training Manual. Ms. Jablonski has completed Chapters 5 and 6 of the manual. Mr. Bennett will send these chapters to all committee members when he receives them.

Mr. Gary Bennett reported that Mr. Ted Coopwood, Executive Secretary, NELAC, would like for each standing committee to send their final chapter revisions to Dr. Jim Pearson, Chair of the Coordinating Committee as soon as possible. They were due April 15.

Dr. Charles Hartwig, NELAC Chair, wants the Assessor Training Manual "in place" before any contracts associated with training providers are approved.

Mr. John Counts, representing the State of Washington and speaking in behalf of ASTPHLD, stated that the organization is actively developing assessor training courses and would be interested in becoming a training provider for NELAC. Roy Covert, speaking on behalf of the AIHA, stated that the organization would also be interested in becoming a training provider.

The committee discussed placing the proposed training agenda on the NELAC Bulletin Board. After discussing the lists of pros and cons, it was decided to place the document on the bulletin board and let the interested parties critique it.

Mr. Bennett concluded the announcements by suggesting that the remainder of the conference call be directed toward addressing the comments of the Illinois EPA. Mr. Bennett proposed that the committee's responses to the issues raised by the Illinois EPA be incorporated into the minutes of the conference call. This was unanimously agreed upon.

Issues - Illinois EPA

Issue #1 a) 3.2.1, paragraph 1 - Illinois strongly believes that minimum criteria for the education and training of assessors be developed and approved prior to adoption as NELAC standards.

Response: The committee references section 3.2.2 which describes assessor education and experience requirements and notes that this section has already been approved by the conference. The committee does not favor more prescriptive education and experience requirements at this time.

- b) Illinois recommends that one training program be developed. At a minimum, Illinois further recommends that the EPA approve and oversee the assessor training program. The program may be provided by a third party.

Response: The committee notes that section 3.2.1, paragraph 3, states that accrediting authorities, accrediting (assessor) bodies, or other entities may provide training programs after NELAP approval. Section 3.2.1 has been approved by NELAC. The committee believes that a single training program is not practical and may not be able to meet the demand for training.

Issue #2 3.2.1, paragraph 3 - Training: "When the NELAC has completed the development and promulgation..." Illinois' understanding is that the NELAP will not be promulgated as final rules in the Federal Register.

Response: The committee's intent was not to indicate that the rules would be published in the Federal Register, but simply approved by the NELAC voting members. However, the committee can see where the wording might create confusion and will petition the NELAC chair for an editorial change to delete the words "and promulgation".

Issue #3 In Section 3.2.2, Basic Qualifications, what will be the status of assessors currently working for the accrediting authority? The Illinois EPA recommends the addition of a grandfather clause to cover current assessors.

Response: At the next voting conference, the committee will propose that the following language be added to the end of the second paragraph of Section 3.2.2:

"Assessors employed by accrediting authorities (either directly or third party) when the authority is granted NELAP recognition (see section 6.6) are exempt from the requirement to undergo training with a qualified assessor during four or more actual on-site assessments, provided they have previously conducted four assessments and been judged proficient by the accrediting authority. Assessors employed by accrediting authorities on the date the NELAP is fully operational must meet the education, experience, and training requirements specified in this section within five years of that date."

Issue #4 3.2.3.f. - Illinois would like clarification on how assessors will be judged on their ability to communicate effectively. If the communication skills/requirements cannot be clarified/enforced, the section should be stricken.

Response: The committee notes that this language is very similar to that in ISO Standard 10011-2 on assessor qualifications. The committee believes this requirement is critical to an assessor performing effectively, and can be adequately judged by the accrediting authority acting as the assessor's employer.

- Issue #5 3.4.5, paragraph 3 - Clarification is needed regarding the CBI clearance of assessors. Who will give assessors clearance and how is CBI clearance given?
- Response: The committee notes that this section is not approved and is still under revision and promises to consider the comments of the Illinois EPA. The draft presented at the February interim meeting indicates that assessors must "have CBI access training" rather than "clearance". The committee feels that the training can be given in the assessor training course and will investigate whether a formal "CBI authorization" is required.
- Issue #6 The Illinois EPA feels that the 30-day time frame allowed for a laboratory to develop and complete corrective actions is unrealistic. The Illinois EPA formally proposes that Chapter 3, Section 3.5.6 be amended to reflect a 90-day corrective action period.
- Response: The interpretation that corrective action must be completed within 30 days is incorrect. The section states that the "applicant laboratory must submit a plan of corrective action....to address all deficiencies noted in the report not later than 30 days from when the report is received." This does not require the laboratory to complete the corrective action within 30 days. The process for submittal of the plan and completion of the corrective action is covered in complete detail in section 4.1.4.
- Issue #7 Section 3.6.3, Checklists, notes that the On-Site Assessment Committee will be developing or adopting standardized checklists for the assessors review of test methods. Will the checklist be part of the NELAC standards to be commented on by all interested parties or will the checklist be inserted into the NELAC standards without comments?
- Response: All supplementary material developed by the committee, including the Assessor Training Manual, laboratory evaluation checklists, associated forms, etc. will be published on the NELAC bulletin board and submitted for approval by the conference.
- Issue #8 On-Site Assessment, Chapter 3. Section 3.2.1 states that the NELAC specifies the minimum level of education and training for assessors. Section 3.6.1 states that the NELAC will develop a manual(s) for on-site assessors..." Constitution and Bylaws, section B.5, states that the On-Site Assessment Committee generates procedures for the on-site assessments and publishes standard checklists based on these procedures. This committee also establishes the frequency of inspection and the minimum education, experience, and training requirements of the assessors. Program Policy and Structure, Section 1.1.1 and 1.4.1, states that the NELAC is a standards setting body and supports a NELAP, and section 1.4.1 states that NELAC does not function as an assessor

body, oversee or approve assessor bodies, or administer any of the main elements of the accreditation program.

If the goal of the NELAC standards is to promote consistency and uniformity, the Illinois EPA recommends that the On-Site Assessment Committee lead and expedite the development of the standards for the assessor training program, assessor manual and checklists. Further, the Illinois EPA feels that the previously listed items should be commented on by all interested parties.

Response: This comment is very similar in content to those observations offered by the Illinois EPA in items 1 and 7. The Committee references the responses for these two items to address item number 8. The committee intends to develop all standards and supporting materials as quickly as resources allow.

Issue #9 Section 3.3.4 states that the accrediting authority is not required to provide advance notice of an assessment. The Illinois EPA recommends that the section be amended to state that the initial on-site assessment of a laboratory must be announced and scheduled for a mutually agreeable time. The Illinois EPA agrees that on-site assessments subsequent to the initial on-site assessment may be announced or unannounced.

Response: This issue was the subject of intense debate from voting members and contributors during previous committee meetings. The consensus of most States was that they did not want to be required to announce on-site assessments, either initial or follow-up. The committee believes that the vast majority of on-site assessments will be announced for logistical reasons. The committee also notes that nothing in Section 3.3.4 prohibits an accrediting authority from adopting a policy of announced visits for all initial assessments.

Issue #10 Section 3.1, paragraph 1 states that the on-site assessment is an integral and requisite part of a laboratory accreditation program and will be one of the primary means of determining a laboratory's capabilities and qualifications. The Illinois EPA recommends that Section 3.3.1 be amended to include the requirement that an on-site assessment be successfully completed prior to the initial accreditation of a laboratory by the primary accrediting authority. This recommendation is consistent with the Illinois EPA's position that interim accreditation be deleted from Chapter 4, Section 4.5.

Response: The committee believes that an accrediting authority will not grant accreditation to any laboratory unless that laboratory completes the on-site assessment to the accrediting authority's satisfaction. Since the comment appears to be directed at interim accreditation rather than on-site assessment, the committee believes that the Accreditation Process committee should address this concern.

Issue #11 Section 3.4.5, paragraph 2, refers to a NELAP assessment confidentiality notice. The Illinois EPA recommends that the elements of the form be listed in Chapter 3. Also, the Illinois EPA recommends that the On-Site Assessment Committee expedite the development of this notice.

Response: The committee will have a copy of this form posted on the bulletin board for review prior to the July '97 NELAC national meeting.

Issue #12 The placement of section 3.5.3, Records Review, implies that items a-q must be reviewed as part of the on-site assessment. The Illinois EPA does not feel that it is feasible to review all the listed items during the on-site assessment. The Illinois EPA feels that an on-site assessment of this type would place an inordinate strain on the resources of the laboratories and accrediting authorities. The Illinois EPA recommends that the section be reworded and amended to state that if section 3.5.3. items (a) through (q) have not been assessed prior to the on-site assessment (see 3.4.3, Information collection and review), the items must be evaluated during the on-site assessment. Thus, an accrediting authority is not required to review all of the listed items during the on-site assessment, nor would an accrediting authority be precluded from reviewing and verifying all of the listed items during the on-site assessment.

Response: The committee fails to see the implication noted by the Illinois EPA. Section 3.5.3 states that items a-q must be examined as part of an accreditation assessment. The section does not state that the records must be reviewed during an on-site assessment. Section 3.4.3 specifically states that "Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual site visit." Thus, taken together in context, Sections 3.4.3 and 3.5.3 give the assessors the flexibility to determine which records they wish to review prior to the site visit and which they will review during the site visit.

The next conference call was scheduled for Wednesday, April 30, 1997 from 12:30 to 2:30 p.m. EST.

Attachment A

**List of Participants
On-Site Assessment Committee Teleconference
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